

REMARKS/ARGUMENTS

Reconsideration of the Examiner's rejection of the present application is requested respectfully in view of the following remarks.

STATUS OF THE CLAIMS

At the time of the present Office Action, claims 1 to 8, 11 to 14 and 18 to 26 were pending in this patent application. Claims 11 and 12 have been amended to correct a spelling error. Claims 18-22 have been canceled, without prejudice. No claim have been added. Therefore, claims 1 to 8, 11 to 14, and 23 to 26 are presented for consideration.

SUMMARY OF OFFICE ACTION

Claims 11-14 and 26 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement.

Claims 1-5 stand objected to under 37 CFR §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim.

All claims were found not to be allowable.

THE REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 11 to 14 and 26 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking reasonable enablement for treating atrial fibrillation or flutter. Applicant respectfully traverses this rejection.

As an initial point, applicants wish to point out that the treatment of "atrial fibrillation or flutter" is only the subject of rejected claims 13 and 14. Claims 11, 12 and 26 are directed to methods for the treatment or prevention of arrhythmias, which are not discussed by the Examiner. Therefore, applicants submit that no outstanding grounds for rejection have been asserted against claims 11, 12 and 26.

In regard to the rejection of claims 13 and 14, applicants first wish to point out that the present application is a division of US App. No. 10/252385, which issued as US Pat. No. 6686395 ('395), which was a division of US App. No. 09/698078, which issued as US Pat. No. 6531495 ('495). These parent and grandparent patents are directed to different groups of

compounds from the present application, but include method of treatment claims essentially the same as those in the present application. Reference is made to claims 7 to 12 of the '395 patent and claims 8 to 14 of the '495 patent. These patent applications were reviewed by the present examiner, and the issue of enablement was raised during those prosecutions and answered in detail to the satisfaction of the Examiner.

The Examiner has rejected the present claims as not enabling the treatment or prevention of the K⁺ channel mediated conditions of atrial fibrillation or flutter. As stated in the specification, the claimed compounds act on the Kv1.5 potassium channel and inhibit potassium current described as the "ultra-rapidly activating delayed rectifier" ("I_{K_{ur}}") in the human atrium. Therefore, the compounds are particularly suitable for the treatment and prophylaxis of atrial arrhythmias such as atrial fibrillation or atrial flutter. (Spec. at page 2, lines 16-19) This action carries benefits for the treatment and prevention of K⁺ channel mediated illnesses. Moreover, and contrary to what is asserted by the Examiner, those skilled in the art are capable of identifying patients with K⁺ channel mediated illnesses and treating them as described in the present specification.

For example, one mechanism for ending arrhythmias, or preventing their formation, is to increase the myocardial refractory time by prolongation of the action potential. (Spec. at page 3, lines 12-14) Inhibition of the I_{K_{ur}} channel potassium outward current is a particularly effective method for the prolongation of the atrial action potential. (Spec. at page 4, lines 4-6) Therefore, it makes sense that the claimed compounds, which can prolong the atrial action potential, can prevent the formation of arrhythmias, a K⁺ mediated illness. Note particularly the discussion in the specification at page 4, lines 1-13.

Each of the above-cited portions of the specification is accompanied by references to supporting articles by well-known authorities in recognized academic journals. Copies of these and other supportive journal articles can be provided to the Examiner upon request.

The above discussion provides a reasoned basis for concluding that the claimed compounds and compositions containing them can be used for the treatment of atrial fibrillation and atrial flutter as set forth in claims 13 and 14, as well as for the treatment and prevention of arrhythmias as set forth in claims 11, 12 and 26. Those skilled in the art would be able to practice these methods by following the teaching in the specification of, for instance, example routes of administration, excipients and vehicles for use in the pharmaceutical formulations, and

example daily doses outlined on pages 27-29 of the specification. For all of these reasons, the Examiner is respectfully requested to reconsider and withdraw the present enablement rejection under 35 U.S.C. §112, first paragraph.

THE OBJECTION UNDER 37 CFR §1.75(c)

The Examiner has objected to claims 1-5 as improper dependent claims (although obviously claim 1 is independent) for failing to further limit the subject matter of a previous claim. Applicants respectfully traverse this objection and contend that each dependent claim duly includes limitations on the scope of the respective claims from which they depend. It is further submitted that due to the complex nature of the chemical formula set forth in claim 1 *et seq.*, the complexity of the dependent claims is needed to provide clear and unambiguous definitions to the limitations contained therein.

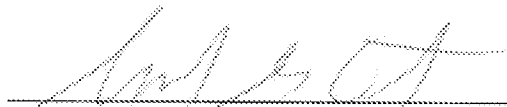
Some of the limitations of the dependent claims are as follows, although additional limitations may also be present. Claim 2, depending from claim 1, differs in the scope of the definitions of R(16), R(17) and R(19). Claims 3 and 4, both depending from claim 2, include various changes in the scope of R(3), as well as R(2) and R(4). Claim 5, depending from claim 4, differs in the scope of R(4), R(5), R(6), R(7), R(8), R(14) and R(16). Claim 6, depending from claim 5, differs in the scope of R(1), R(5), R(6), R(7), R(8), R(30) and R(31). Claim 23, depending from claim 4, differs in the scope of R(14), R(16), R(17), R(30) and R(31). Claim 24, depending from claim 5, differs in the scope of R(14) and R(16), as well as R(30) and R(31). Claim 25, depending from claim 4, differs in the definitions of R(14) and R(16). In each case, the dependent claims include limitations at least on the recited variables. Thus, it is submitted that all of these dependent claims are fully in conformance with the requirements of 37 CFR §1.75(c)

CONCLUSION

For all of the above reasons, it is submitted that all of the claims in the present application are now in condition for allowance, and action to that effect is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees or credit any overpayment resulting from this Amendment to Deposit Account 18-1982.

Respectfully submitted,



Ronald G. Ort, Reg. No. 26,969
Attorney for Applicant

sanofi-aventis U.S. LLC.
Patent Department
Route #202-206 / P.O. Box 6800
Bridgewater, NJ 08807-0800
Telephone (908) 231-2551
Telefax (908) 231-2626